NOTICE OF PROPOSED RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 6. DEPARTMENT OF HEALTH SERVICES

COMMUNICABLE DISEASES AND INFESTATIONS

PREAMBLE

1. **Articles and Sections Affected** **Rulemaking Action**

R9-6-101	Amend
Exhibit I-A	Repeal

2. **The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**

Authorizing statute: A.R.S. § 36-136(A)(7) and (F)

Implementing statutes: A.R.S. §§ 36-132(A)(1) and 36-136(H)(1)

3. **A list of all previous notices appearing in the Register addressing the proposed rules:**

Notice of Rulemaking Docket Opening: 14 A.A.R. ????, October 10, 2008

4. **The name and address of agency personnel with whom persons may communicate regarding the rulemaking:**

Name:	Ken Komatsu, State Epidemiologist
Address:	Arizona Department of Health Services
	Bureau of Epidemiology and Disease Control
	150 N. 18th Ave., Suite 150
	Phoenix, AZ 85007
Telephone:	(602) 364-3587
Fax:	(602) 542-2722
E-mail:	komatsk@azdhs.gov
	or
Name:	Kathleen Phillips, Esq.
	Administrative Counsel and Rules Administrator
Address:	Arizona Department of Health Services
	Office of Administrative Counsel and Rules
	1740 W. Adams, Suite 200
	Phoenix, AZ 85007
Telephone:	(602) 542-1264
Fax:	(602) 364-1150
E-mail:	phillik@azdhs.gov

5. An explanation of the rules, including the agency's reasons for initiating the rules:

A.R.S. § 36-136(H)(1) states that the Arizona Department of Health Services (Department) shall "define and prescribe reasonably necessary measures for detecting, reporting, preventing, and controlling communicable and preventable diseases." The Department has adopted rules to implement this statute in 9 A.A.C. Chapter 6. The definitions for terms used throughout Chapter 6 are contained in R9-6-101, along with Exhibit I-A, to which reference is made in the definition of "vaccinia-related adverse event." This rulemaking is adding the definition of "medical evaluation," which is currently used in Article 2 and Article 12, and will be used in the amended definition of "vaccinia-related adverse event." With the amended definition of "vaccinia-related adverse event," Exhibit I-A will no longer be used and is being repealed. This rulemaking conforms to rulemaking format and style requirements of the Governor's Regulatory Review Council and the Office of the Secretary of State.

6. A reference to any study relevant to the rules that the agency reviewed and either proposes to rely on in its evaluation of or justification for the rules or proposes not to rely on in its evaluation of or justification for the rules, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The Department did not review or rely on any study related to this rulemaking package.

7. A showing of good cause why the rules are necessary to promote a statewide interest if the rules will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

As used in this summary, annual costs/revenues are designated as minimal when less than $1,000, moderate when between $1,000 and $10,000, and substantial when greater than $10,000. Costs are listed as significant when meaningful or important, but not readily subject to quantification.

The Department believes that the proposed rule will result in at most a minimal cost to the Department, a local health agency, a health care institution, a correctional facility, or a health care provider required to report. The clarification of what a "medical evaluation" means and the amended definition of "vaccinia-related adverse event" will provide a minimal benefit to the Department, a local health agency, a health care institution, a correctional facility, and a health care provider.

The Department has determined that the benefits related to public health outweigh any potential costs associated with this rulemaking.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name:	Ken Komatsu, State Epidemiologist
Address:	Arizona Department of Health Services
	Bureau of Epidemiology and Disease Control
	150 N. 18th Ave., Suite 150
	Phoenix, AZ 85007
Telephone:	(602) 364-3587
Fax:	(602) 542-2722
E-mail:	komatsk@azdhs.gov
	or
Name:	Kathleen Phillips, Esq.
	Administrative Counsel and Rules Administrator
Address:	Arizona Department of Health Services
	Office of Administrative Counsel and Rules
	1740 W. Adams, Suite 200
	Phoenix, AZ 85007
Telephone:	(602) 542-1264
Fax:	(602) 364-1150
E-mail:	phillik@azdhs.gov

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rules, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rules:

The Department has scheduled the following oral proceeding:

Date:	November 17, 2008
Time:	9:30 a.m.
Location:	150 N. 18th Ave., Room 540A
	Phoenix, AZ 85007
Close of record:	4:00 p.m., November 17, 2008

A person may submit written comments on the proposed rules no later than the close of record to either of the individuals listed in items #4 and #9.

A person with a disability may request a reasonable accommodation, such as a sign language interpreter, by contacting Ruthann Smejkal at (602) 364-1230 or smejkar@azdhs.gov. Requests should be made as early as possible to allow time to arrange the accommodation.

11. **Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:**

Not applicable

12. **Incorporations by reference and their location in the rule:**

Not applicable

13. **The full text of the rule follows:**

TITLE 9. HEALTH SERVICES

CHAPTER 6. DEPARTMENT OF HEALTH SERVICES

COMMUNICABLE DISEASES AND INFESTATIONS

ARTICLE 1. GENERAL

Section

ARTICLE 1. GENERAL

R9-6-101. Definitions

In this Chapter, unless otherwise specified:

1. No change
2. No change
3. No change
4. No change
5. No change
6. No change
    a. No change
        i. No change
            (1) No change
            (2) No change
        ii. No change
            (1) No change
            (2) No change
    b. No change
        i. No change
        ii. No change
7. No change
8. No change
9. No change
10. No change
11. No change
12. No change
13. No change
    a. No change
        i. No change
        ii. No change
        iii. No change
    b. No change
    c. No change
    d. No change
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15. No change
16. No change
17. No change
    a. No change
    b. No change
    c. No change
    d. No change
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21. No change
    a. No change
    b. No change
    c. No change
22. No change
23. No change
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    a. No change
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28. No change
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30. No change
31. No change
    a. No change
    b. No change
    c. No change
    d. No change
32. No change
33. No change
34. No change

35. No change

36. No change

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51. No change

a. No change

b. No change

52. No change

53. No change

54. “Medical evaluation” means an assessment of an individual’s health by a physician, physician assistant, or registered nurse practitioner.

~~54.~~55. No change

a. No change

b. No change

~~55.~~56. No change

~~56.~~57. No change

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~~62.~~63. No change

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~~67.~~68. No change

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e. No change

f. No change

g. No change

~~68.~~69. No change

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~~70.~~71. No change

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~~71.~~72. No change

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~~75.~~76. No change

a. No change

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c. No change

d. No change

~~76.~~77. No change

~~77.~~78. No change

~~78.~~79. No change

~~79.~~80. No change

~~80.~~81. No change

~~81.~~82. No change

~~82.~~83. “Vaccinia-related adverse event" means ~~any of the reactions described in Exhibit I-A~~ a reaction to the administration of a vaccine against smallpox that requires medical evaluation of the reaction.

~~83.~~84. No change

~~84.~~85. No change

~~85.~~86. No change

~~86.~~87. No change

Exhibit 1-A: ~~Case Definitions for Suspected Clinically Significant Adverse Events~~ Repealed

~~Adverse Event~~	~~Case Definition~~
~~Anaphylaxis~~	~~Hypotension, tachycardia, nausea, vomiting, collapse in first hours after smallpox vaccination~~
~~Eczema vaccinatum~~	~~• Extensive vesicular and pustular eruption anywhere, or~~ ~~• More limited vesicular or pustular eruption occurring in more than one site typically affected by atopic dermatitis (inner elbow folds, back of knees, face)~~ ~~Comments: Usually occurs in a patient with a history of skin disease, especially atopic dermatitis. Usually occurs concurrently or shortly after the local vaccinial lesion in a vaccine or 5-19 days after exposure in a contact. Patients usually have signs of moderate to severe systemic illness, including fever, malaise, prostration.~~
~~Fetal vaccinia~~	~~Generalized vaccinial type rash (vesicular, pustular, or ulcerative) in newborn of vaccinated mother~~
~~Generalized vaccinia (severe)~~	~~Disseminated maculopapular or vesicular lesions with either:~~ ~~a. Symptoms of moderate to severe systemic illness, including fever, malaise, prostration; or~~ ~~b. Documented immunodeficiency~~
~~Inadvertent inoculation (severe)~~	~~Extensive vesicular and pustular lesions at distal sites in a vaccinee or any sites in a contact, which are not generalized but may involve large contiguous areas, including sites of other skin injury.~~ ~~Comments: Sites usually consistent with physical transfer of virus from primary vaccination site and most commonly are the face, eyelids, nose, mouth, lips, genitalia, and anus.~~
~~Ocular vaccinia~~	~~Inflammation involving peri-ocular soft tissue or the eye itself (blepharitis, conjunctivitis, keratitis, or iritis) in a recent vaccinee or contact of vaccinee~~
~~Post vaccinial encephalitis or encephalomyelitis~~	~~Any change in mental status (confusion, delirium, somnolence) or in sensorimotor function (altered sensation, weakness, paresis) occurring 6-15 days after vaccination~~
~~Progressive vaccinia~~	~~• Progressive expansion of the vaccination site lesion, often with necrosis, or~~ ~~• Failure to heal the vaccinia lesion(s), or~~ ~~• Disseminated vaccinia lesions~~ ~~In association with~~ ~~• Minimal or no inflammatory response to the vaccinia lesion(s)~~ ~~Comments: Either (a) rapid progression of the vaccination site lesion with minimal inflammation at any time, or (b) progression at any rate with minimal inflammation after 15 days should suggest progressive vaccinia.~~
~~Rashes (severe)~~	~~Generalized rash with mucosal ulceration or symptoms of moderate to severe systemic illness, including fever, malaise, prostration~~